INFORMED CONSENT

TITLE: EVALUATION OF THE SAFETY AND EFFICACY OF AN ACNE TREATMENT DEVICE

PROTOCOL NO: DCS-46-20

AIRB Approved
Robert J. Staab PhD
DATE 10.15.2020

INVESTIGATOR: Zoe Diana Draelos, M.D.

TELEPHONE: (336) 841-2040, 24-Hour Number

INTRODUCTION

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

ZIIP is conducting this study and your study doctor is being paid by ZIIP to conduct the study.

COVID SAFETY PROCEDURES

You will be requested to wear a mask covering your nose and mouth at times while at the research center. All study staff will wear a mask and gloves, if they will touch you. Plexiglass barriers will be in place if Dr. Draelos needs to examine you without your mask. The research center has installed a cold plasma generator on all heating/air-conditioning units to kill viral and bacterial particles in the air. All surfaces and furniture in the office are disinfected immediately after the subject vacates a chair or leaves a room.

STUDY PURPOSE

You are being asked to take part in a 12-week research study. The purpose of this study is to evaluate the effect of a device on the appearance of acne.

Approximately 50 people will participate in this study. The study will include using a device on your face in the areas afflicted by acne for 4 minutes on 3 non-consecutive days. Your study participation will last approximately 12 weeks and will include up to 5 visits (Baseline, Week 2, Week 4, Week 8, and Week 12).

STUDY PROCEDURES

If you wish to participate in this research study, you will be asked to read and sign this informed consent. In order to determine if you qualify to participate in this study, the following procedures will be performed:

- You will be asked about your skin and your medical history, including any prescription or over-the-counter medications you may be taking.
- The study doctor will examine your facial skin for acne. The doctor will count the acne lesions on your face. All of the assessments will be visual.
- You must present to the research center with a clean washed face.
- You must continue to use your own self-selected moisturizer, nonmedicated cleanser, and sunscreen for the duration of the study.
- You must not change any of your other facial cosmetics during the study.
- You will complete a questionnaire and the study doctor will also complete a questionnaire.
- You will be given a conductive glycerin-based gel to apply to your areas of acne. You will then be given a device to rub over the areas afflicted with acne on 3 non-consecutive days per week. You will use the conductive gel and device for the first time at the research center.
- You will complete a questionnaire and the study doctor will complete a questionnaire after you use the conductive gel and device for the first time at the research center.
- You will be given a diary to record your conductive gel and device use. You must use the conductive gel and device on 3 non-consecutive days per week.
- You will be asked to return to the research center in 2 weeks with a clean washed face. A reminder text will be sent to you just before your return visit.

You will return to the research center at week 2 and week 4 and week 8, and week 12 for the following activities:

- The study doctor will examine the skin on your face and assess your acne. The study doctor will count your acne lesions. All of the assessments will be visual.
- You and the study doctor complete a questionnaire regarding the condition of your skin.
- Your study diary, conductive gel, and device will be examined.
- You will receive a reminder text prior to each visit.
- Your study participation will end after the week 12 visit.

Each of your visits will last approximately one hour. 20 people will be invited by the investigator to participate in the photography portion of the study. If you are selected and agree to participate, a photograph will be taken of your central, right, and left face at each visit. You will put your head on a chin rest and a camera will take a picture. The chin rest will be rotated so images can be taken of your central, right, and left face.

STUDY INSTRUCTIONS

The following instructions are to be followed when using the device:

1. Begin with clean, dry skin.
2. Apply the electroconductive media gel provided to you liberally over any areas where you have acne.
3. Turn on your device by pressing the button at the top. You will hear one beep.
4. Place the device on top of your skin. Lights will illuminate under the device when both silver probes come in contact with your skin. Both probes must keep contact with skin throughout treatment.
5. Follow along with the video, slowly making circles with the top probe (the one farthest away from the charging port) over acne. (You may feel a tingling sensation during treatment. That is normal.)
6. Do not treat a single spot more than one minute at a time. Only treat areas with visible acne.
7. At the end of treatment, your device will beep twice and turn off.
8. After treatment, wipe your device clean with a tissue, being careful to avoid the charging port. Spray the device and a second tissue lightly with rubbing alcohol and wipe again, remaining careful to avoid the charging port.
9. Store safely away from water, moisture or debris. After treatment, wipe your device clean with a tissue before putting it away.

CHARGING:

When you see the orange light flashing while using your device, it's time to charge.

To charge, plug in the charging cable provided. The orange light will remain illuminated while charging. You will know that your device is completely charged when the orange light is no longer on.

STUDY REQUIREMENTS AND RESTRICTIONS

In addition to making the required study visits, you must use the provided study gel and device. You must use them correctly. You must use the same moisturizer, nonmedicated cleanser, sunscreen, and cosmetics for the duration of the study. **You must not share the study products with others.**

You may not participate in this research study if you are participating in any other research study.

There are contraindications and warnings associated with device use that you must be aware of during the study. These contraindications and warnings are presented below:

CONTRAINDICATIONS

ZIIP should not be used in the following areas:

- Breast area
- Directly on top of the eyelid
- Midline of neck (bone of neck)
- Groin area
- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device because this may cause electric shock

WARNINGS
Do not submerge the device in water or any other liquid(s). If you store your ZIIP in an area such as a bathroom counter, ensure the product does not come in contact with water or other liquid(s).

ZIIP should not be used by:
• Children
• Pregnant Women
• People subject to seizures
• People with cancer/tumors
• People with a cardiac pacemaker
• People with implanted defibrillators/stimulators
• People with electronic implanted devices

If you have any medical concerns, such as a severe medical illness, epilepsy or seizures, or recent facial surgery, please consult your doctor before using ZIIP.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when a ZIIP device is in use.

Stimulation should not be applied over, or in proximity to cancerous lesions, or applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, broken capillaries, varicose veins, etc. Men should shave before use as hair can interfere with the conductivity of the electrodes. Facial area under a beard or mustache cannot be treated.

Do not apply stimulation across your chest as the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.

The long-term effects of stimulation are not known.

RISKS

As with any topical product, skin irritation (such as rash, tenderness, burning, or itching, swelling), may occur at the site of application. These effects are expected to be temporary and should disappear as soon as the study product is stopped. The conductive gel is not intended for use in the eye. If the product

should accidentally enter the eye, rinse thoroughly with abundant lukewarm water. Do not use the acne device anywhere else except on your acne lesions.

There is also a possibility that you may have an allergic reaction to one of the ingredients in the study products. If you have an allergic reaction, your skin may get red, swollen, blistered, and itchy. You should contact Dr. Draelos immediately at 336-841-2040 should you experience any of these problems.

Any problems or adverse events your experience will be followed to resolution.

PREGNANCY RISKS

Using the study products may involve unknown risks to an embryo, fetus (unborn baby), or nursing infant. Therefore, if you are pregnant, planning to become pregnant, or are breast-feeding, you cannot participate in this study.

UNFORESEEN RISKS

There may be other risks that are unknown, including an allergic reaction. If you experience an allergic reaction, an attempt will be made to determine the cause. Dr. Draelos will evaluate you and determine the best way to address the reaction.

NEW FINDINGS

Any new information which is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

BENEFITS

It is possible that your participation in this study will result in improvement of the appearance of your acne. There are other preparations designed for acne that are available for purchase. If you would like additional information, please ask Dr. Draelos. Your participation in this study will help to provide information as to the ability of the study device to improve acne.

PAYMENT FOR PARTICIPATION

For your participation in the study, you will receive a total of up to $250: no payment for baseline, $50 for Week 2, $50 for Week 4, $50 for Week 8, $100 for Week 12. If you do not complete the study, you will be paid for the visits you do complete according to this schedule. These funds will be paid by personal check at the week 12 visit.

If you are invited to participate in the photo portion of this study, you will receive a total of up to $300: no payment for baseline, $50 for Week 2, $50 for Week 4, $75 for Week 8, $125 for Week 12. If you do not complete the study, you will be

paid for the visits you do complete according to this schedule. These funds will be paid by personal check at the week 12 visit.

If you have any questions about your compensation for participation, please contact Dr. Draelos at the phone number listed on page one of this consent form.

COSTS

There will be no charge to you for your participation in this study. The study products, study-related procedures, and study visits will be provided at no charge to you and your insurance company.

CONFIDENTIALITY

Records of your participation in this study will be held confidential so far as permitted by law. Information from this study will be submitted to the sponsor. Study-related medical records, including photographs, which identify you and the consent form signed by you, will be inspected by the sponsor and may be inspected and/or copied to the FDA, Department of Health and Human Services (DHHS) agencies, governmental agencies in other countries, and the Institutional Review Board (IRB). Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study forms. The study doctor will keep this personal health information in your study related medical records (that we will refer to as "your records"). In addition, the study doctor may obtain, and include in you records, information regarding your past, present and/or future physical or mental health and/or condition, such as medical records from your primary care physician. Your records may include other personal information (such as social security number, medical record numbers, date of birth, photographs, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (which we will refer to as "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization". Therefore, you may not participate

in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing you are agreeing to allow the study doctor and staff to use your PHI to conduct this study; to monitor your health status; possibly, to develop new tests, procedures, and commercial products.

By signing this authorization, you are also agreeing to allow the study doctor to disclose PHI as described below:

- Your PHI may be disclosed to the sponsor of this study and any agents, representatives, or consultants working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may disclose it to the United States Food and Drug Administration (FDA) or similar regulatory agencies in the United States and/or foreign countries. The study staff will assign a code number and/or letters to your records, which means you, will not ordinarily be identified in the records sent to the sponsor; however, the sponsor may look at your complete study records, which would identify you. In addition the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct. The sponsor may wish to observe the skin evaluations done by the study doctor, and as such, will observe you.

- The Institutional Review Board (IRB) may have access to your PHI in relation to its responsibilities as an institutional review board.

These disclosures also help ensure the information related to the research is available to all parties who may need it for research purposes.

Your identity will remain confidential and, except for the disclosures described above, will not be shared with others unless law requires such disclosure. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this form, not to see or copy your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will never expire unless and until you revoke (cancel or withdraw) it. You have a right to revoke it at any time. If you revoke your authorization, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must send a written notice to the study doctor's office, stating that you are revoking your Authorization to Use or

Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue your participation in this study.

COMPENSATION FOR INJURY

If you experience a research-related problem, appropriate medical treatment will be provided to you by the sponsor at no additional cost, provided that your personal insurance does not cover the cost of the treatment. You will not lose any of your legal rights as a research subject by signing this consent form.

VOLUNTARY PARTICIPATION/ WITHDRAWAL

Your participation in this study is voluntary. You can decide not to participate or withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled and without effect on your future medical care. If you discontinue your participation in this study, you may be asked to return for a final study visit for your safety. You must contact the study doctor or study staff at the phone number listed on page one of this form and inform them of your decision to withdraw. You must return the study product to the study facility whether or not you complete the study. This will complete your study activities.

The study doctor or sponsor may remove you from the study without your consent for any of the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if it is discovered that you do not meet the study requirements, at the discretion of the study doctor, if the study is canceled or for administrative reasons.

QUESTIONS OR EMERGENCIES

You are encouraged to ask questions at any time during the study. In the event you experience any changes or have concerns or further questions about the study, please call the study doctor at the phone number listed on page one of this form during or after office hours.

For questions regarding the rights of human subjects, you may contact the Allendale Institutional Review Board (AIRB), Robert Staab, Old Lyme, CT, 860-434-5872.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

PHOTOGRAPHY CONSENT

I consent to have identifying photographs taken of my face by the study doctor or a photographer approved by the study doctor.

These photographs will be used as part of the study-related record. If, in the judgment of the study doctor, medical research, teaching or corporate communication of the study results will benefit from their use, the study doctor has my consent to use or permit others to use these photographs for the following purposes:

1. Publication in a medical article or text book
2. As part of a scientific exhibit
3. To illustrate medical lectures given to medical students or other professional groups
4. Publication to communicate study results.
5. To use photos by the Company to promote product based on successful results.

These photographs of my face can used in both print and electronic format for the purposes mentioned above. I will not be identified by name in any such use of these photographs. I have read and understand this consent form. I give my authorization for the use of my photographs as described above.

CONSENT

I have read and understand the informed consent document for this study. I volunteer to take part in this research study involving an acne treatment device. The study product I use and the information I will be told about the study product is confidential. I have been asked to return all study products upon completion of the study or if I discontinue participation. I will follow directions and only apply the study product as directed. I will not give or share the study product with others.

The risks and study procedures have been fully and clearly explained to me. I have had the opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to take part in this research study. I do not give up any of my legal rights as a research subject by signing this consent form. I will receive a copy of this signed consent form.

I authorize the release of my study-related medical records, including identifying facial photographs, to the sponsor, the FDA, DHHS agencies, governmental agencies in other countries and the IRB. In the event I experience any adverse effect, I agree to have a photograph taken of the site to be provided to the sponsor of the study.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent Date

SUBJECT SIGNATURE PAGE

Printed Name of Subject (First Name, Middle Initial, Last Name)

Signature of Subject (First Name, Middle Initial, Last Name) Date (mm/dd/2020)